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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,217	12/09/2005	Jeffrey H. Yanof	PHUS030182US	4972

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EXAMINER
EVOY, NICHOLAS LANE

ART UNIT	PAPER NUMBER
4136	

MAIL DATE	DELIVERY MODE
06/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,217	YANOF ET AL.	
	Examiner	Art Unit	
	NICHOLAS L. EVOY	4136	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/10/2007 and 12/9/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because the reference number "191" for the medical device should be recited in Figs. 2-4B. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The abstract of the disclosure is objected to because the abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: The term "This application claims the benefit of U.S. provisional application serial no. 60/479,576 filed June 18, 2003 and U.S. provisional application serial no. 60/512,491 filed October 18, 2003, both of which are incorporated herein by reference." on Pg. 1, line 1 should be recited as --This application is filed under 35 U.S.C. 371 of PCT/IB04/02020, filed June 17, 2004, which claims the benefit of U.S. Provisional Application Serial No. 60/479,576, filed June 18, 2003 and U.S. Provisional Application Serial No. 60/512,491, filed October 18, 2003, both of which are incorporated herein by reference.--, so as to clarify the status. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 4, 5 and 11-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 4, 5, 13 and 14, the recitation therein is unclear and confusing. It is suggested that the term "extending from the selected virtual target point and out from the body of the patient" should be recited as --extending from the selected virtual target point and the body of the patient--, so as to clarify the confusion.

Regarding claims 11-13 and 15, the antecedent basis for "providing the imaging device" (as per claim 11), "the providing step" (as per claim 12), "the providing means for selecting the virtual trajectory", "means for identifying a virtual path" (as per claim 13) and "providing the

connector portion of the guide apparatus" (as per claim 15) has not been clearly set forth. In addition, as per claims 12-18, the recitation therein is unclear, indefinite and confusing. It is not understood as to whether these claims are independent or dependent claims. If they are independent claims, then all the required method steps are missing. If they are dependent claims, then the preamble are inconsistent with their respective parent claims. Further, as per claim 13, the term "medical device and apparatus while" should be recited as --medical device and the guide apparatus while--.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-8, 10-17 and 19 rejected under 35 U.S.C. 102(b) as being anticipated by Kwoh (US Pat. No. 5,078,140).

Regarding Claim 1, 10 and 19, Figs. 4 and 5 of Kwoh discloses a system, method or apparatus for inserting a medical device into a patient including an imaging device scanning the patient to generate a volumetric image data set of the patient, a human readable device for displaying an image of the patient derived from the volumetric image data set, means for selecting a virtual trajectory defining a path for inserting the medical device into the patient, robotic means on the imaging device and movable into selected positions relative to the imaging device, and a guide apparatus to direct movement of the medical device relative to the patient

disposed on the robotic means, the guide apparatus comprising: a connector portion coupling the guide apparatus with the associated imaging device at a distal end of the robotic means (from column 2, line 62 to column 3, line 9); a main body portion supported relative to the associated imaging device by the connector portion (see Figs. 1, 4 and 5); a gripping area formed at a first end of the main body portion, the gripping area adapting the guide apparatus for manual gripping by an associated operator (i.e. when the disclosed robotic system is in a mode for manual surgical operation; see column 6, line 57 to column 7, line 2); and, a holding area formed at a second end of the main body portion, the holding area holding the medical device in an orientation suitable for motion relative to the patient along a selected linear path, the holding area being operative to translate the medical device along the selected linear path in response to manual force applied by the associated human operator at the gripping area (see from column 5, line 17 to column 10, line 4).

Regarding Claim 2 and 11, Kwoh discloses that the imaging device is a CT scanner, an MRI scanner, a CCT scanner, a fluoroscope, a SPECT scanner, a PET scanner, or a combination of the foregoing (i.e. for specific use in CT, MRI, ultrasound or PET imaging; see column 2, lines 61-68).

Regarding Claim 3 and 12, Kwoh discloses that the medical device is an ablation probe or a biopsy needle (i.e. using the system for a needle biopsy surgery; see column 9, lines 6-12).

Regarding Claim 4 and 13, Kwoh discloses that the means for selecting the virtual trajectory includes means for selecting a virtual target point in the image of the patient by identifying a first coordinate in the image of the patient, and means for identifying a virtual path extending from the selected virtual target point and out from the body of the patient (i.e. utilizing

stereotactic software for use with a CT scanner and interfacing with a robotic arm for surgeon interaction; see column 6, line 5-23).

Regarding Claim 5 and 14, Kwoh discloses that the robotic means is adapted to move the guide apparatus into a position whereat the medical device is in an orientation suitable for motion relative to the patient along the selected linear path coincident with the virtual path extending from the virtual target point and out from the body of the patient (i.e. a system that moves linearly in line with a predetermined surgical path; see column 5, line 23 to column 6, line 23).

Regarding Claim 6 and 15, Kwoh discloses that the connector portion of the guide apparatus includes a one of a linear slide joint and a prism joint (i.e. a system that moves linearly in line with a predetermined surgical path; see Figures 4-6).

Regarding Claim 7 and 16, Kwoh discloses that the position feedback device provided on the connector portion of the guide apparatus for providing a feedback signal indicating a position of the guide apparatus relative to the patient (i.e. encoders present that provide position and velocity feedback; see column 4, lines 1-6) and means for displaying an image of the medical device as it is physically moved relative to the patient based upon feedback signal, together with the image of the patient and the virtual path (i.e. the N-shaped locators that provide spatial position references that show up in cross-sectional images obtained by operating the CT scanner; see column 6, lines 24-40).

Regarding Claim 8 and 17, Kwoh discloses that the holding area is formed of an x-ray transmissive material (i.e. the N-shaped locators that provide spatial position references that

show up in cross-sectional images obtained by operating the CT scanner; see column 6, lines 24-40).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 9, 18 and 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Kwoh (US Pat. No. 5,078,140) in view of Johnson (US Pat. No. 3,893,813).

Regarding claims 9, 18 and 20, it is noted that Kwoh does not specifically disclose that a holding area includes a set of tweezers-like arm portions adapted to grip the medical device in a V-shaped groove formed by the arm portions. However, Figs. 1-3 and 6 of Johnson teaches that such feature of using a clamp with tweezers-like arm portions for use with chemical equipment in a laboratory setting, such as with pipettes and other precision instruments (see from column 1, line 64 to column 2, line 33) is old and well known. Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system, method or apparatus of Kwoh with the feature of a set of tweezers-like arm portions of the medical device holding mechanism as taught by Johnson as both Kwoh and Johnson are directed to the system, method or apparatus for inserting a medical device into a patient, so as to give a sure way for mounting medical devices to the surgical system while still preserving the accuracy of the device and the sturdiness of the mount.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICHOLAS L. EVOY whose telephone number is (571)270-1388. The examiner can normally be reached on M-F 7:30-5:00, Alternating Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin M. Lateef can be reached on (571)270-1493. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NLE
6/16/2009

/Joe H Cheng/
Supervisory Patent Examiner
Art Unit 4136